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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,694	10/18/2005	Yoshitaka Izumoto	IZUMOTO 1	2025

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EXAMINER	
DUFFY, PATRICIA ANN	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,694	IZUMOTO ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,39-47,49-62,66-68,71,72,76 and 77* is/are pending in the application.

4a) Of the above claim(s) *51-62, 66-68, 71, 72, 76 and 77* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,39-47,49 and 50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESPONSE TO AMENDMENT

The amendment filed 9-29-08 has been entered into the record. Claims 2-38, 48, 63-65, 69, 70 and 73-75 have been cancelled. Claims 1, 39-47, 49-62, 66-68, 71, 72, 76 and 77 are pending. Claims 1, 39-47, 49 and 50 are under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Election/Restrictions

This application contains claims 51-62, 66-68, 71, 72, 76 and 77 as drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Rejections Withdrawn

The title of the invention is not descriptive is withdrawn.

The rejection of claim 27 and every claim dependent thereon are rejected under 35 U.S.C. 112, second paragraph is withdrawn based on Applicants amendment to the claims.

The rejection of claims 1, 25, 26, 27, 28, 29, 30, 33 and 34 rejected under 35 U.S.C. 102(b) as being anticipated by Fersht et al (WO 00/75346, 14 December 2000) is withdrawn in view of the amendment to the claims.

The rejection of clams 1, 25, 26, 27, 28, 29, 30, 33 and 34 under 35 U.S.C. 102(b) as being anticipated by Scholz et al (WO 03/000878, published 3 January 2003) is withdrawn in view of the amendment to the claims.

The rejection of claims 1 and 23-50 under 35 U.S.C. 102(b) as being anticipated by Furutani et al (WO 02/052,029, published 04 July 2002) in light of Furutani et al US

7,276,355 which is an English language equivalent of the WO document) is withdrawn in view of the amendment to the claims.

The rejection of claims 63-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Furutani et al (WO 02/052,029, published 04 July 2002) in view of Scholz et al (WO 03/000878, published 3 January 2003) and Harlow et al, (Antibodies A Laboratory Manual, Cold Spring Harbor Press, 1988, Ch. 5, pages 53-137) is withdrawn in view of the cancellation of the claims.

New Rejections Based on Amendment to the Claims

Claims 1, 39-47, 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Furutani et al (WO 02/052,029, published 04 July 2002) in view of Scholz et al (WO 03/000878, published 3 January 2003), Harlow et al, (Antibodies A Laboratory Manual, Cold Spring Harbor Press, 1988, Ch. 5, pages 53-137) and Sambrook et al, (Molecular Cloning A Laboratory Manual, Second Edition, Cold Spring Harbor Labooratory Press, 1989, page 17.3).

Furutani et al teach fusion proteins comprising GroEL chaperonin subunits from 1-7 in a fusion protein with target protein produced by recombinant means wherein the target protein is fused N or C terminal or both with a chaperonin and at least two subunit chaperonins are linked by a peptide bond (see Figure 2, elements 2-4; Figure 3 and Figure 7). The fusion protein comprises 1-20 chaperonin subunits liked to on another and a desired protein linked via the N-terminus or the C-terminus. The fusion protein has at least one linking region where the linking region may be cleaved by a restriction protease to release the target protein. Furutani et al teach there is a fusion protein comprising chaperoning subunits and a desired protein being linked by a peptide linkage to the chaperoning subunits is accommodated inside of the chaperonin ring. The chaperonin ring may have formed a 2 layer structure associated non-covalently via a ring plane. The chaperonin used is not particularly limited and may be derived from bacteria, archaeum

and eukaryotes and includes GroEL (Example 8). The desired protein is not particularly limited and includes the serotonin receptor (5H1A) fusion protein with GroEL (Example 8). A sequence to be cleaved with a restriction protease such as thrombin, enterokinase or active blood coagulation factor can be arranged in a linkage between the chaperoning subunit and the desired protein and also in a linkage between the chaperonin subunits to cleave the desired protein off the fusion protein with the restriction protease. Furutani et al differs by not teaching the fusion protein combined with an adjuvant.

Scholz et al teach fusion protein immunogens comprising two chaperone produced by recombinant technology where the fusion comprises chaperone-antigen-chaperone wherein at least one linkage is a peptide liner of 10-100 amino acids (claim 14) wherein the linker comprises a proteolytic cleavage site (claim 20) wherein the polypeptide is a polypeptide from an infectious organism and used for immunization and is combined with a pharmaceutically acceptable excipient (see claims 21-26). Target polypeptides are described at pages 6-7 including human gene products.

Harlow et al teach conventional adjuvant formulations to make immunogenic compositions for antibody production (see pages 96-99).

Sambrook et al teach that it was well known in 1989 that it is often useful to produce a fusion protein for use as an antigen (page 17.3, line 1) and provides the advantages of some fusions.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to add an adjuvant according to Harlow to the fusion protein compositions of Furutani et al because Sambrook et al teach that that it is often useful to produce a fusion protein for use as an antigen and Scholz et al teach that fusion proteins comprising folding factors can be used as immunogens.

Applicants' arguments have been carefully considered but are not persuasive. Applicants argue that there is no direct suggestion in any of the references to add a

adjuvant to the fusion protein of Furutani et al. This is not persuasive, folding factor fusion proteins were known in the art as successful immunogens and it would have been obvious to add an adjuvant to the fusion protein of Furutaini et al because Scholz et al teach that fusion proteins can be used to make antibodies to a target antigen and Sambrook teach that it is useful to produce a fusion protein for use as an antigen.

Further, *In re* Fine, 837 F.2d 1071, 1075, 5U.S.P.Q.2d 1959 (Fed. Cir. 1988) states that under section 103 a *prima facie* case of obviousness can be established by showing some objective teaching in the prior art **or *that knowledge generally available to one of ordinary skill in the art can lead the individual to combine the references***. See also *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). Furthermore, the courts have held "The test of obviousness is not express suggestion of the claimed invention in any or all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them." See *In re Rosselet*, 146 USPQ 183, 186 (CCPA 1965). "There is no requirement (under 35 USC 103(a)) that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art." *Motorola, Inc. v. Interdiqital Tech. Corp.,* 43 USPQ2d 1481, 1489 (Fed. Cir. 1997). Finally, an obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. , 2007 U.S. LEXIS 4745, 2007 WL 1237837, at *12 (2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."). This composition is merely a combination of known elements, yielding predictable results.

Status of Claims

Claims 1, 39-47, 49 and 50 stand rejected. All other pending claims are withdrawn from consideration.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-

0855. The examiner can generally be reached on M-Th 7:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisors, Robert Mondesi can be reached at 571-272-0956.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/
Primary Examiner